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REMARKS

Applicant respectfully requests reconsideration of the present application in view of the following remarks.

I. PRIOR ART REJECTIONS

Claim Rejections Under 35 U.S.C. §103 (a)

Claims 1-19 stand rejected under 35 U.S.C. §103 (a) as being unpatentable over U.S. Patent No. 6,127,428 to Lundgren et al. (hereafter "Lundgren") in view of U.S. Patent No. 5,792,090 to Ladin et al. (hereafter "Ladin") and further in view of U.S. Patent No. 6,139,876 to Kolta et al (hereafter "Kolta"). This rejection is respectfully traversed.

Applicant's claimed invention, as set forth in Claim 1, provides, *inter alia*, a method of increasing tissue oxygenation in mammals, comprising applying a superoxygenated composition to a tissue surface for a time sufficient to increase the subepithelial partial oxygen pressure from about 30% to about 120% above baseline pO_2 .

As set forth in the Office Action, Lundgren provides a method of increasing tissue oxygenation in mammals by applying a superoxygenated composition to a tissue surface for a period of time to increase pO_2 from 30-120%. According to the Office Action, Lundgren is also alleged to teach various other aspects, such as the use of microbubbles, different formulations, the use of the method to treat skin conditions. As set forth in the Office Action, Lundgren does not teach the use of the methods to increase pO_2 in the skin of humans having a wound, burn, or ulcer.

As set forth in the Office Action, Ladin provides a method to increase pO_2 in the skin of humans having burns, ulcers, or scalds. As set forth in the Office Action, Lundgren does not teach the relationship between wound infection, wound healing, the increase in partial pressure of oxygen and the motivation for such application of a composition that can cause such increased tissue oxygenation at the sub-epithelial level.

As set forth in the Office Action, Kolta provides a method of treating a wound infected by aerobic bacteria and the use of gelatin with oxygen contained therein, with the increased pO_2 in the gel facilitating healing of the wound.

It is respectfully submitted that the combination of Lundgren, Ladin and Kolta fails to teach or suggest Applicant's claimed invention. Initially, it is noted that the combination of the

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references is improper as the technologies are in diverse fields wherein the teachings of each reference could not be expected to achieve Applicant's claimed invention. Lundgren is directed to increasing the oxygenation of internal tissues and organs inside an individual systemically. Ladin and Kolta are directed to application of oxygenation to permit wound healing on a person's skin. It is respectfully submitted that one of ordinary skill in the art, when attempting to promote wound healing, would not look to technologies directed to the treatment of organs, and one of ordinary skill in the art, when attempting to increase the pO_2 in an organ, would not look to technologies directed to the treatment of skin traumas.

Even if there was proper motivation for combining Lundgren, Ladin and Kolta, it is respectfully submitted that the combination of Lundgren, Ladin and Kolta would still fail to teach or suggest Applicant's claimed invention. As claimed by Applicant, a superoxygenated composition is applied to a tissue surface for a time sufficient to increase the **subepithelial** partial oxygen pressure from about 30% to about 120% above baseline pO_2 (emphasis added). The subepithelial layer is located about 1 mm below the skin surface. The epithelial layer above the subepithelial layer is a barrier layer in regards to different materials, such as oxygen gas. Accordingly, applying a composition to the skin surface will not achieve a corresponding degree of subepithelial partial oxygen pressure due to this barrier effect. Rather, the partial pressure needed to achieve a subepithelial partial oxygen pressure increase of 30-120% above baseline is substantially higher than achieving a 30-120% partial oxygen pressure at the skin surface. As such, Lundgren fails to teach or suggest Applicant's claimed invention as Lundgren teaches a partial pressure increase of greater than 5% (Office Action) at the surface of the tissue, not at the subepithelial layer.

Applicant's claimed invention delivers a superoxygenated composition that has a partial pressure high enough to penetrate the epithelial layer to produce a subepithelial partial oxygen pressure increase of 30-120% above baseline. In Lundgren, the partial pressures are on the order of about 100 mmHg to achieve the results of increasing the partial oxygen pressure 30-120% above baseline at the tissue surface. In the present invention, however, the partial pressures are in the order of 1500+ mmHg at the skin surface to achieve a subepithelial partial oxygen pressure increase of 30-120% above baseline. This is shown, in part for some embodiments, by the delivery of the superoxygenated composition at pressures of 50-110 psi (app. 2500-5500 mmHg) at page 12, lines 24-29. As each person is different, and the selected level above baseline may

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vary by treatment, the exact partial pressure needed to achieve a subepithelial partial oxygen pressure increase of 30-120% above baseline may vary, but in any instance, the partial pressures of the compositions used in Lundgren will not achieve this level of treatment.

Ladin and Kolta, alone or in combination, fail to remedy this deficiency. Neither Ladin nor Kolta teach or suggest a method of applying a superoxygenated composition to a tissue, wherein the composition has a partial pressure high enough to penetrate the epithelial layer to produce a subepithelial partial oxygen pressure increase of 30-120% above baseline. As such, the combination of Lundgren, Ladin and Kolta fails to teach or suggest Applicant's claimed invention.

For at least the reasons given above, Applicant respectfully submit that Claim 1 is allowable over the prior art of record. Furthermore, as Claims 2-19 recite additional claim features and depend from Claim 1, these claims are also allowable over the prior art of record.

II. FORMAL MATTERS

Double Patenting

Claims 1-7 and 11-12 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 17-23 and 25-26 of U.S. Patent No. 6,649,145. This rejection is respectfully traversed.

Applicant respectfully submits that the subject matter claimed in claims 17-23 and 25-26 of U.S. Patent No. 6,649,145 is patentably distinct from the subject matter claimed in the present application. Nevertheless, to expedite prosecution, Applicant submits herewith a Terminal Disclaimer. Accordingly, Applicant respectfully submits that this rejection is moot and be withdrawn.

III. CONCLUSION

For at least the reasons given above, Applicant submits that Claims 1-19 define patentable subject matter. Accordingly, Applicant respectfully requests allowance of these claims.

The foregoing is submitted as a full and complete Response to the Office Action mailed August 11, 2004, and early and favorable consideration of the claims is requested.

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Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is respectfully requested to contact Applicant's representative at the telephone number listed below.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 50-0951.

Respectfully submitted,

Date: 11/12/04



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